

## REMARKS

A check for the fees for a three month extension of time and an RCE accompanies this response. Any fees that may be due in connection with the filing of this paper or with this application during its pendency may be charged to Deposit Account No. 06-1050. If a Petition for Extension of time is needed, this paper is to be considered such Petition.

Claims 9-14 and 58-73 are pending in this application. Claims 58 and 59 are amended for clarity and to advance this application to allowance. The amendments represent a bona fide attempt to address the minor issues raised under 35 U.S.C. §112, second paragraph. Claim 58 is amended to recite that the change in phenotype is compared to a control. Claim 58 also is amended to recite that the oligonucleotide family members are designed to encode sequences that are complementary to sequences that are distributed throughout the target mRNA. Basis for the amendments can be found in the specification as originally filed. For example, the application describes that phenotypic changes are compared to control cells, on page 22, line 6, - page 23, line 15, and in the Example 7, which states that a control is a mock infected cell. One of skill in the art would recognize that any change, such as a phenotypic change, is compared to a control. The application describes the family of oligonucleotides throughout. The language was included in the amended claims, mailed August 3, 2005. For example, basis can be found in the description of Figures 1A-1C on page 5 and in the Figures, which are provided to describe what is meant by a family of oligonucleotides. See, also ,page 11, which states that the family is based on sequences distributed throughout the target nucleic acid molecules. Claim 59 is amended to recite the antecedent in claim 58. These amendments should place the case into condition for allowance as they address all issues raised by the Examiner.

### **THE REJECTION OF CLAIMS 8-14 AND 58-74 UNDER 35 U.S.C. §112, SECOND PARAGRAPH**

Claims 9-14, and 58-73 are rejected under 35 U. S. C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention for reasons addressed in turn below. Reconsideration of the grounds for this rejection is respectfully requested in view of the amendments herein and the following remarks.

#### **Relevant Law**

Definiteness of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular application disclosure, (2) the teachings of prior art, and (3) the

interpretation claims would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. Claims need only "reasonably apprise those skilled in the art" of their scope and be "as precise as the subject permits." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. den., 480 U.S. 947 (1987). The Court in *Orthokinetics, Inc v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081 (Fed. Cir. 1986) held that a claim limitation requiring that a pediatric wheelchair part be "so dimensioned as to be insertable through the space between the doorframe of an automobile and one of the seats" is definite. The Court stated:

The phrase 'so dimensioned' is as accurate as the subject matter permits, automobiles being of various sizes. As long as those of ordinary skill in the art realized that the dimensions could be easily obtained, § 112, 2d requires nothing more. The patent law does not require that all possible lengths corresponding to the spaces in hundreds of different automobiles be listed in the patent, let alone that they be listed in the claims.

1 USPQ2d at 1088.

When one skilled in the art would understand all of the language in the claims when read in light of the specification, a claim is not indefinite.

Applicant is unaware of any requirement that terms be defined in the claims when one of skill in the art can readily determine the meaning of the term based on the description and definitions provided in the specification. In this respect, applicant is entitled to be its own lexicographer [see, e.g., MPEP 2111.01, "Applicant may be his or her own lexicographer as long as the meaning assigned to the term is not repugnant to the term's well known usage and utilize terms within the claims that are clear from a reading of the specification"]. In *re Hill*, 73 USPQ 482 (CCPA 1947). When applicant has provided definitions in the specification, the claims are interpreted in light of such definition.

35 U.S.C. § 112, second paragraph requires only reasonable precision in delineating the bounds of the claimed invention. The claim language is satisfactory if it reasonably apprises those of skill in the art of the bounds of the claimed invention and is as precise as the subject matter permits. *Shatterproof Glass Corp. v. Libby-Owens Ford Col.*, 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir), cert dismissed, 106 S. Ct. 340 (1985).

The amount of detail required to be included in the claims depends on the particular invention and the prior art and is not to be viewed in the abstract, but in conjunction with whether the specification is in compliance with the first paragraph of 35 U.S.C. § 112. If the claims, read in light of the specification, reasonably apprise those skilled in the art of the

utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more:

[i]t is not necessary that a claim recite each and every element needed for the practical utilization of the claimed subject matter (*Bendix Corp. v United States*, 600 F.2d 1364, 1369, 220 Ct. Cl. 507,514, 204 USPQ 617, 621 (1979); See, also, *Carl Zeiss Stiftung v. Renishaw plc*, 20 USPQ2d 1094, 1101).

### **Analysis**

1. Claim 58, and claims dependent therefrom, are alleged to be vague and indefinite in the recitation of the "antisense strand that, when expressed as RNA, binds to an mRNA transcribed from the target nucleic acid sequence," (see lines 15-16), because this statement suggests that the antisense RNA produced from the sense stranded of the cloned double stranded DNA, targets an mRNA other than the mRNA product "coded for by a sample nucleic acid in the target nucleic acid" as set forth in the preamble of the claimed method.

Claim 58 is amended to recite:

a sense strand and an antisense strand, wherein the sense strand codes for an antisense strand that, when expressed as RNA, that binds to an mRNA sequence transcribed from the sample nucleic acid in the target nucleic sequence so that expression of a product from the target nucleic acid is inhibited . . .

Thus, it should be clear that the sense strand encodes RNA that binds to mRNA transcribed from the sample nucleic acid in the target nucleic acid as recited in the preamble. If this amendment does not address the issue raised by the Examiner, the undersigned would appreciate a telephonic interview to address the issue. .

2. Claim 58 also is rejected because "the nature of the 'oligonucleotide family' recited in claim 58, line 7, is vague and indefinite. The language describing the oligonucleotide family, previously present in claim 8, whose limitations were incorporated into claim 58, and inadvertently deleted in the previous response has been reintroduced.

3. Claim 58 also is rejected as incomplete in failing to mention "a control, un-transfected host cell, such that changes in phenotype can be assigned to one particular antisense RNA targeting one particular gene target, by comparison of the transfected host cell, and the un-transfected host cell." While, the explicit recitation of a control should not be necessary, since a claim is not a recipe, but describes the metes and bounds of an applicant's claimed method, the claim is amended to include this language in order to advance this application to allowance.

4. Claim 59 and claims 60-63, and 70, which depend on claim 59, are rejected as improperly dependent on claim 58 because lines 2-3 recite "a catalytic domain that cleaves an mRNA sequence transcribed from the target nucleic acid." The Examiner states that phrase is suggestive of multiple mRNA sequences transcribed from the target nucleic acid and that claim 58 states that its intended objective is to assign a function associated with a product coded for by a "sample nucleic acid sequence in a target nucleic acid molecule." Therefore, it is alleged that:

it is unclear if the entire scope of claim 59 and those claims dependent therefrom, further limits claim 58, since the method of claim 59 involves wherein the RNA (assuming the RNA here refers to antisense RNA produced from the sense strand in claim 58) cleaves an mRNA sequence transcribed from the target nucleic acid.

Applicant respectfully disagrees.

Attention is directed to MPEP 608.01(n), which defines the requisites for proper dependency of claims. The test for determining proper dependency of a claim is that:

... it shall include every limitation of the claim from which it depends (35 U.S.C. 112, fourth paragraph) or in other words that it shall not conceivably be infringed by anything which would not also infringe the basic claim.

A dependent claim does not lack compliance with 35 U.S.C. 112, fourth paragraph, simply because there is a question as to (1) the significance of the further limitation added by the dependent claim, or (2) whether the further limitation in fact changes the scope of the dependent claim from that of the claim from which it depends. The test for a proper dependent claim under the fourth paragraph of 35 U.S.C. 112 is whether the dependent claim includes every limitation of the claim from which it depends. The test is not one of whether the claims differ in scope. [emphasis added, see MPEP 608.01(n)].

Thus, claim 59, as a dependent claim, includes all limitations of the claim(s) upon which it depends. To advance prosecution, however, claim 59 is amended to repeat the language from the base claim and recite that the RNA "is produced from the sense strand of binds to an mRNA sequence transcribed from the sample nucleic acid in the target nucleic sequence."

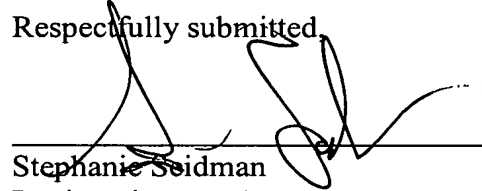
\* \* \*

Applicant : James Keck *et al.*  
Serial No. : 09/601,997  
Filed : December 15, 2000

Attorney's Docket No.: 21121-007US1/2307US  
**Preliminary Amendment**

In view of the above, reconsideration and allowance of the application are respectfully requested.

Respectfully submitted,



---

Stephanie Seidman  
Registration No. 33,779

Attorney Docket No. 21121-007US1/2307US  
**Address all correspondence to:**  
Stephanie Seidman  
Fish & Richardson P.C.  
12390 El Camino Real  
San Diego, California 92130  
Telephone: (858) 678-5070  
Facsimile: (202) 626-7796  
email:seidman@fr.com